

NOV 17 2000

K002724

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## 510(k) Summary

### 4.1 Introductory Information

Submitter's Information: Numa, Inc.  
10 Northern Boulevard, Unit 12  
Amherst, NH 03031  
Tel: 603-883-1909  
Fax: 603-883-0839

Contact Person: Larry Smith, President

Date of Submittal: June \*\*\*\*\*, 2000

### 4.2 Device Names

Trade or proprietary name: NumaLink™

Common name: Nuclear Medicine Image Translation System

Classification name: Nuclear Tomography System Accessory (21CFR892.1310, Class II)

### 4.3 Predicate Device Identification

We are claiming substantial equivalence of NumaLink to the GammaCon™ Image Translation System (K931376), originally submitted by Numa.

### 4.4 Device Description

NumaLink is a PC and Windows-based image translation system that translates nuclear medicine images from one format to another.

### 4.5 Intended Use

The intended use of NumaLink is to provide computer software on a PC-based hardware platform for translation of nuclear medicine images from one format to another. NumaLink provides no image processing capability.

### 4.6 Summary of Technical Characteristics Compared to Predicate Device

NumaLink operates in the Windows environment, while GammaCon is DOS-based. NumaLink allows for user-customization of translations, while GammaCon does not.

#### **4.7 Brief Description of Non-Clinical Tests**

Image translations were performed on test images in the same manner as using the GammaCon image translation system, thus providing an identical testing situation and full support of substantial equivalence.

#### **4.8 Conclusions from Testing**

Testing showed accurate translation of all formats tested into the formats desired. Substantial equivalence was confirmed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 17 2000

Larry Smith  
President  
Numa, Inc.  
10 Northern Boulevard, Unit 12  
Amherst, NH 03031

Re: K002724  
NumaLink™ (Nuclear Tomography System Accessory)  
Dated: August 29, 2000  
Received: August 31, 2000  
Regulatory class: II  
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) NUMBER (IF KNOWN): K002724

DEVICE NAME: NumALink

INDICATIONS FOR USE:

NumALink is a computer software product that translates nuclear medicine images from one format to another.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

David A. Legman  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K002724